(c) Prior investigations of a lens shall not be considered adequate to justify an investigational study involving human subjects unless the conditions of the prior investigations of the lens are comparable to the conditions of the proposed investigational study.

§ 813.30 Food and Drug Administration review of and action on an application.

(a) Upon receipt of an application for an investigational device exemption submitted in accordance with this subpart, the Food and Drug Administration will notify the sponsor of the date of such receipt and inform the sponsor that the investigational study may not be begun until 30 days after the date of the agency's receipt of the application, unless the agency has decided to waive the 30-day time requirement and so informs the sponsor.

(b) An application for an investigational device exemption shall be deemed to be approved on the 30th day after the Food and Drug Administration received the application unless, on or before such day, the Commissioner finds that the application does not meet the requirements of this part and by order disapproves the application, stating his reasons therefor, or finds the application deficient and requests additional information or suggests revisions, or approves the application with modifications. If the Commissioner requests additional information or suggests revisions, the sponsor may treat the application as disapproved for purposes of requesting a regulatory hearing under Part 16 of this chapter.

(c) The Commissioner may by order disapprove an application if he makes any of the following findings:

(1) The application contains an untrue statement of a material fact or omits material information required by § 813.20.

(2) The report of prior investigations of the intraocular lens is inadequate to support a conclusion that it is reasonably safe to begin or continue the proposed investigational study.

(3) There is reason to believe that the lens may be unsafe or ineffective when used for the purpose or in the manner for which it is to be investigated.

(4) The investigational plan described in the application is not a reasonable plan, in whole or in part, for a scientific investigation to determine whether the investigational device is safe or effective.

(5) The methods, facilities, and controls used for the manufacturing, processing, packing, storage, or implantation of the lens do not assure adequately the safety and effectiveness of the lens.

(6) The sponsor's proposed use of the lens is not intended solely for an investigational study, since it is being or is to be sold or otherwise commercially distributed in a manner not justified by the requirements of the investigational study and not permitted by this part.

(7) The proposed investigational study on which the application is submitted does not conform to procedures, conditions, or requirements prescribed in this part.

(8) The proposed investigational study subjects human subjects to undue risks. In assessing risks, the Commissioner shall consider, among other things, the factors prescribed in § 813.66(f).

(d) The Commissioner shall notify the sponsor of an approval, disapproval, or approval with modifications of an application. The notification shall contain the order of the approval, disapproval, or approval with modifications and a complete statement of the reasons for the order. An order that is a notification of disapproval or approval with modifications shall advise the sponsor that he has recourse to an opportunity for a regulatory hearing pursuant to Part 16 of this chapter.

(e) The Commissioner may in his discretion decide not to disapprove an application for which there are grounds for disapproval if he concludes that risks do not outweigh the benefits to subjects.

§ 813.35 Withdrawal of an exemption.

(a) The Commissioner may by order withdraw an exemption granted under this part if he makes any of the following findings:

(1) The application for such exemption or any subsequent report contains

an untrue statement of material fact or omits material information required by §§ 813.20, 813.39, or Subpart C of this part.

(2) The report of prior investigations of the device is inadequate to support a conclusion that it is reasonably safe to continue the investigational study involving human subjects.

(3) There is reason to believe that the investigational device may be unsafe or ineffective when used for the purposes or in the manner for which it is investigated.

(4) The investigational plan described in the application is not a reasonable plan, in whole or in part, for a scientific investigation to determine whether the investigational device is safe or effective.

(5) The methods, facilities, and controls used for the manufacturing, processing, packing, storage, or installation of the investigational device do not adequately assure its safety and effectiveness.

(6) The investigational study is not being conducted in accordance with the investigational plan submitted to the Food and Drug Administration or the institutional review committee; or any change in, or deviation from, the investigational plan was not approved as required by § 813.39 and § 813.105.

(7) The sponsor's use of the investigational device is not solely for an investigational study since it is being or is to be sold or otherwise commercially distributed in a manner not justified by the requirements of the investigational study and not permitted by this part.

(8) The sponsor has failed to submit an application for premarket approval of the device when requested to do so by the Food and Drug Administration pursuant to § 813.46(d).

(9) The investigational study does not conform to procedures, conditions, or requirements prescribed under this part.

(10) The investigational study subjects human subjects to undue risks. In assessing risks, the Commissioner shall consider, among other things, the factors prescribed in § 813.66(f).

(11) The process of review or monitoring undertaken by the institutional review committee that is monitoring the study is inadequate.

(b) The Commissioner may in his discretion decide not to disapprove an application for which there are grounds for disapproval if he concludes that the risks do not outweigh the benefits to subjects.

(c) An order under this section shall include a complete statement of the reasons for the Commissioner's action. Such order shall be issued only after the sponsor has been afforded an opportunity for a regulatory hearing pursuant to Part 16 of the chapter, except that the order may be issued before providing an opportunity for such hearing if the Commissioner determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health or safety.

(d) An exemption that has been withdrawn under section may be reinstated if the sponsor satisfies the Commissioner that the grounds for withdrawal no longer apply.

[42 FR 58889, Nov. 11, 1977; 43 FR 1940, Jan. 13, 1978]

§ 813.38 Confidentiality of data and information in an application.

(a) The existence of an application for an investigational device exemption will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public dislosure of all data and information in the Food and Drug Administration file concerning the application shall be handled in accordance with the provisions established in § 814.9.

(c) Notwithstanding the provisions of § 814.9 of this chapter, the Food and Drug Administration shall disclose upon request to an individual in whom an intraocular lens has been used a copy of any adverse reaction report relating to such use.

[42 FR 58889, Nov. 11, 1977, as amended at 53 FR 11253, Apr. 6, 1988]